

EXHIBIT N

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

LP MATTHEWS, L.L.C.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 04-1507 (SLR)
)	Honorable Sue L. Robinson
BATH & BODY WORKS, INC.,)	JURY TRIAL DEMANDED
and)	
LIMITED BRANDS, INC.,)	
and)	
KAO BRANDS CO. (f/k/a THE ANDREW)	
JERGENS COMPANY),)	
and)	
KAO CORPORATION,)	
)	
Defendants.)	

**Expert Report of John Carson, M.S.
Regarding Greenspan United States Patent No. 5,063,062**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	QUALIFICATIONS.....	2
III.	INFORMATION CONSIDERED.....	2
IV.	EXHIBITS	3
V.	WORK PERFORMED	3
VI.	ANALYSIS AND OPINIONS TO BE EXPRESSED	3
	A. Basis of Opinions Formed	3
	B. Opinion of Invalidity.....	5
VII.	CONCLUDING REMARKS	7

APPENDICES

Appendix A – Professional Qualifications

Appendix B – Information Considered

Appendix C – Tables 1-4

Appendix D – Other Testing and Results

I. INTRODUCTION

Counsel for Limited Brands, Inc. and Bath & Body Works, Inc. (collectively "the Limited") has retained me to act as a technical expert in this case. I submit this report pursuant to Rule 26(a)(2) of the Federal Rules of Civil Procedure. I have personal knowledge of the information contained in this report, and if called to testify, I could and would competently do so regarding this information.

At this time, I have been asked to prepare a report setting forth my position on the invalidity of claims 6 and 9 of United States Patent No. 5,063,062 ("the '062 patent"), which I understand to be the only patent claims at issue in this case. More specifically, I was retained to evaluate the validity of claims 6 and 9 of the '062 patent. This evaluation was to include laboratory evaluations of various aspects of the '062 patent as well as evaluation of existing literature and technical data.

This report summarizes the subject matter and opinions about which I expect to testify in the subject litigation. I have based the opinions contained in this report on information presently available to me. If I receive additional information later on, I will consider it and I reserve the right to state further opinions in response to additional information.

I am not connected in any way with any party to this litigation. I am an independent Chemical and Product Formulation and Development Consultant working for Carson Product Development, Inc. My compensation is \$250 per hour for laboratory experiments, data analysis, literature research and evaluation time and \$500 per hour for deposition and trial testimony time. My compensation is not contingent upon the outcome of these proceedings. I have not testified in any other patent infringement cases.

II. QUALIFICATIONS

I received a Bachelors of Science Degree in Chemistry from Stevens Institute of Technology in Hoboken, NJ in 1970. I also earned a Masters of Science Degree in Chemistry from Rutgers University in New Brunswick, NJ in 1976 and a Masters of Business Degree from Monmouth College in Long Branch, NJ in 1979. My educational and professional qualifications are attached as Appendix A.

I am a named inventor on fourteen United States Patents. (See Appendix A). Further, I direct and teach a course in product formulation for the Center for Professional Advancement and teach a course on emulsion technology for the Society of Cosmetic Chemists. I am also an adjunct professor at Fairleigh Dickinson University where I teach a Hair Care Products Formulation and Raw Materials course.

III. INFORMATION CONSIDERED

In forming my opinions, I reviewed and studied the '062 patent, its file history, the prior art cited in that patent, and the file history of a related continuation-in-part application (U.S. application serial no. 07/786,804) ("the '804 application"). I have also considered the information, documents, and materials listed in Appendix B. In addition, I conducted several tests related to formulations disclosed in the '062 patent and its prosecution history. The test methods and results are attached as Appendix C.

IV. EXHIBITS

I expect to use and rely upon exhibits during my deposition and testimony at trial, but I have not finalized the specific details of these exhibits. I may use product samples, product literature and photographs to illustrate and explain various aspects of my testimony. If needed, I may use and rely upon other exhibits as well.

V. WORK PERFORMED

The Limited, through its counsel, has retained me to analyze, among other things, whether Claims 6 and 9 of the '062 patent are invalid in view of technology that was known prior to the filing of the application which led to the '062 patent. In this regard, counsel for BBW has asked me to review the '062 patent, its file history, the cited references, the file history for the related '804 application, and other miscellaneous references through the eyes of one of ordinary skill in the art. In preparing this report, I have reviewed and considered all such materials. I have also considered the appropriate level of skill and knowledge required by one to practice this invention. The following discussion summarizes my invalidity analyses and opinions regarding the '062 patent.

VI. ANALYSIS AND OPINION TO BE EXPRESSED**A. Basis of Opinions Formed**

It is my understanding that a finding of invalidity for obviousness under 35 U.S.C. § 103 requires that the prior art must teach that the elements of the claim would have been obvious to one of ordinary skill in the art at the time of the invention. Further, I understand that a finding of invalidity for obviousness under 35 U.S.C. § 103 in view of a combination of references requires

that all of the elements in the claim would have been obvious to one of ordinary skill in the art at the time of the invention, and that there must be a reason or motivation to combine such references.

I also understand that for a patent to be valid under 35 U.S.C § 112, the specification, when filed, must contain sufficient subject matter as to enable one of skill in the pertinent art to make and use the claimed invention.

I also understand that an applicant, pursuant to C.F.R. § 1.56, has a duty of candor and good faith in dealing with the United States Patent and Trademark Office, and that if she fails to do so her patent may be deemed unenforceable.

I understand that the level of ordinary skill in the art is based on such factors as the education and experience of those working in the field, the types of problems encountered in the art, the complexity of the technology and whether the prior art proposed additional solutions to the problem. I have reviewed the patents, the cited references, various other patents in the field and product formulations. Further, I am currently working in the field as a consultant to the personal care and household products industries. In addition to my educational background, I have over thirty-five years of experience in product formulation and development. As I mentioned in Section II, I am also a professor, and I direct and teach courses in product formulation, raw materials, and emulsion technology. Therefore, I feel that these experiences qualify me to render the opinion that a person of ordinary skill in the art would be someone that has (i) taken some college level chemistry courses and has some experience with product formulation or (ii) a Bachelors of Science degree in Chemistry.

My review of the '062 patent in light of the various references I considered leads me to the conclusion that one of skill in the art would find claims 6 and 9 of the '062 patent to be

invalid for obviousness under 35 U.S.C. § 103 and/or 35 U.S.C. § 112, as more fully explained below and in Appendices C and D.

B. Invalidity

I understand that only claims 6 and 9 of the '062 patent are being asserted by the plaintiff in this case. While I have reviewed all of the claims of the '062 patent, the opinions expressed in this report are directed at claims 6 and 9 only. If additional claims are asserted, I may provide additional opinions, if asked.

In my opinion, at least Claims 6 and 9 of the '062 patent would have been obvious to one having ordinary skill in the art at the time of the invention in view of Dellutri, U.S. Patent No. 4,620,937 ("Dellutri") issued on November 4, 1986 and Juliano et al., U.S. Patent No. 4,014,995 ("Juliano") issued on March 29, 1977. Dellutri teaches a hand cleaner with a pH of 5.5 comprising 20-90% citric oil and the moisturizer aloe vera. Juliano teaches an improved skin formulation with a pH of 5.5 comprising 1-20% oat flour and the moisturizer mineral oil.

It is also my opinion that at least claims 6 and 9 of the '062 patent would have been obvious to one having ordinary skill in the art at the time of the invention in view of Dellutri and Musher, U.S. Patent No. 2,436,818 ("Musher") issued on March 2, 1948. Musher teaches a hand cleaner with a pH of 2-10 comprising 0.3-15% of an oat fraction and the moisturizer lanolin.

Further, it is also my opinion that at least claims 6 and 9 of the '062 patent would have been obvious to one having ordinary skill in the art at the time of the invention in view of Coleman, "D-limonene as a Degreasing Agent," The Citrus Industry, Vol. 56, No. 11, published

in November 1975 ("Coleman") and Musher. Coleman teaches a hand cleaner comprising citrus oil and the moisturizer lanolin.

It is also my opinion that at least claims 6 and 9 of the '062 patent would have been obvious to one having ordinary skill in the art at the time of the invention in view of Coleman and Juliano.

The motivation to combine various combinations of Juliano, Dellutri, and Coleman was first espoused by the Board of Patent Appeals and Interferences when it rejected all of the claims in the '804 application, the continuation-in-part of the '062 patent. More specifically, the Board found that the hypothetical person of ordinary skill in the art would have found it obvious to treat human skin with a composition containing orange oil, oatmeal, and aloe vera.

The bases for these opinions and my more detailed analysis are contained in Tables 1-4 and are attached to this report as Appendix C.

In addition, it is my opinion that at least claims 6 and 9 are invalid under 35 U.S.C. § 112 because the specification does not allow one of ordinary skill in the art to make or use the invention. I was unable to make a stable emulsion using the examples provided in the '062 patent.

It is also my opinion that the '062 patent is unenforceable because the inventors failed to properly exercise their duty of candor and good faith in dealing with the United States Patent and Trademark Office. Contrary to statements made during the prosecution of the '062 patent, I was not able to make a composition which substantiated claims that a cleaning composition containing orange oil would have superior cleaning properties to a cleaning composition containing distilled d-limonene. Notably, it is my understanding that the plaintiff has not proffered, and I have not seen or reviewed, any test results from the inventors which substantiate

their claims. Further, in prosecuting the '062 patent, the applicants made material misstatements regarding the differences between orange oil and d-limonene.

VII. CONCLUDING REMARKS

I have based the opinions expressed in this report on established scientific principles, my analysis of the claim language, and my review of all of the material identified in this report. I used standardized methodology to conduct my investigation, to consider the information listed above, and to analyze the information.

I may modify the opinions expressed in this report if I receive new information through discovery or other means. I understand that as trial preparation continues, I will have the right to supplement or amend this report in the event that I receive additional information pertinent to my opinions. I may testify in more detail within my area of expertise on the issue of invalidity based on prior art to inform the court as to the basis for my opinions, and/or as stipulated by the parties.

I reserve the right to state further opinions in response to additional subject matter that is properly raised during discovery or at trial and that lies within my area of expertise. I may also provide reports in rebuttal to expert reports submitted by the Plaintiff. In addition, I understand that I may express opinions in response to other matters that Plaintiff may raise at or before trial.

In addition to the documents cited in this report, I may develop demonstrative and summary exhibits to enable me to present my opinions clearly to the Court, as mentioned in Section IV. Counsel for the Limited will provide these exhibits to opposing counsel when and as required by orders from the court. I declare that all statements made herein of my own knowledge are true and that those made on information and belief are believed to be true. I

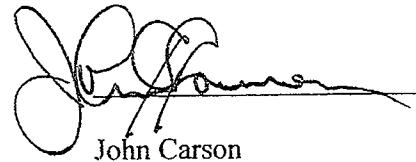
further declare that the report is accurate, true, and correct to the best of my information and belief.

Date: _____

John Carson

further declare that the report is accurate, true, and correct to the best of my information and belief.

Date: Feb 28, 2006



A handwritten signature in black ink, appearing to read "John Carson".

John Carson

APPENDIX A



John C. Carson

CARSON PRODUCT DEVELOPMENT, INCORPORATED

2310 WEST STREET • UNION CITY, N.J. 07087

TEL 201 864 0105 • FAX 201 863 5694

PROFILE

A Personal Care Products formulator with over thirty five years experience in product creation, design, formulation, testing, development and project management. Developed products for major international Personal Care Products companies as well as a major international raw materials supplier. A record of success illustrated by having written magazine articles and co-authored a chapter on Cosmetic Emollients, the issuance of eleven patents and teaching for various organizations and universities. A history of satisfying customer demands through "hands on" R&D and working with Marketing, Manufacturing and Sales to convert ideas into reality.

AREAS OF EXPERTISE

- Product Development
- Product Testing
- Product Commercialization
- Product Scale-up
- Laboratory Start-up
- New Product Conceptualization
- New Product Applications
- New Product Research
- Sales / Marketing Presentations
- Instruments and Microscopes
- Project Leadership
- Resource Management
- Project Coordination
- Laboratory Management
- Teaching / Training

SOME SIGNIFICANT CONTRIBUTIONS

<u>Customer</u>	—	Developed many new personal care product formulations such as: hand and body creams and lotions, shampoos, conditioners, hair sprays, gels, soaps, bath products, and fragrance products for Croda Inc and several major finished goods companies.
<u>Corporate and Cost savings</u>	—	Instrumental in developing new raw materials for Croda Inc as well as instituting processing and product quality improvements.
<u>Science</u>	—	Authored several trade journal articles and co-authored a chapter about emollient ingredients. Taught courses in Emulsion Technology for the Society of Cosmetic Chemists, Fairleigh Dickinson University and City College. Continuing to investigate the properties of liquid crystal and gel phase structures in emulsions.

KEY POSITIONS HELD

<i>Present</i>	CPD, Inc	• President
1988 to 1998	Croda Inc	• Technical Director
1984 to 1988	Cosmair	• Group Leader Fragrance
1979 to 1984	Avon	• Senior Chemist in Hair Care, Bath and Fragrance Groups
1978 to 1979	Shulton	• Senior Chemist Permanent Waves and Hair Sprays
1976 to 1978	J & J Baby	• Scientist - Hair Care
1970 to 1976	Colgate	• Scientist - Antiperspirant Testing, Hair Care, Pharmaceuticals and New Products.
		• Applications Laboratory Manager
		• Group Leader Hair Care



John C. Carson

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EDUCATION

BS - Organic Chemistry
MS - Organic Chemistry
MBA - Management

Stevens Institute of Technology - 1970
Rutgers University - 1976
Monmouth University - 1979

PATENTS

<u>U.S. Patent No.</u>	<u>Title</u>	<u>Issue Date</u>
4,029,236	Two product dispenser with cooperating telescoping cylinders	6/14/1977
4,112,536	Applicator	9/12/1978
4,116,354	Two chambered mixing container	9/26/1978
4,122,976	Dispensing	10/31/1978
4,328,131	Elastic detergent bar of improved elevated temperature stability	5/4/1982
4,554,097	Elastic detergent product containing anionic and amphoteric synthetic organic detergents	11/19/1985
5,302,377	Fatty alkoxylate esters of aliphatic and aromatic dicarboxylic and tricarboxylic acids as emollients	4/12/1994
5,455,025	Non-aqueous emollient compositions for topical application	10/3/1995
5,597,555	Fatty alkoxylate esters of aliphatic and aromatic dicarboxylic acids	1/28/1997
5,693,316	Fatty alkoxylate esters of aliphatic and aromatic dicarboxylic acids	12/2/1997
6,552,171	Hydrolyzed jojoba protein	4/22/2003
6,649,177	Formulations including hydrolyzed jojoba protein	11/18/2003
6,723,310	Hair conditioning formulations	4/20/2004
6,800,736	Hydrolyzed jojoba protein	10/5/2004

APPENDIX B

APPENDIX B

INFORMATION CONSIDERED

A. United States Patents and Applications

1. Goode, U.S. Patent No. 1,550,026 entitled "Face Pack" issued on 8/18/1925.
2. Allen, U.S. Patent No. 2,165,828 entitled "Base, or Emulsifying Vehicle, for Flavoring Agents" issued on 7/11/1939.
3. Musher, U.S. Patent No. 2,273,062 entitled "Stabilization of Oils" issued on 2/17/1942.
4. Musher, U.S. Patent No. 2,282,808 entitled "Stabilization of Essential Oils" issued on 5/12/1942.
5. Musher, U.S. Patent No. 2,436,818 entitled "Cosmetic Preparations" issued on 3/2/1948.
6. Tinnon, et al., U.S. Patent No. 3,095,381 entitled "Cleaning Compositions" issued on 6/25/1963.
7. König, U.S. Patent No. 3,579,454 entitled "Liquid Detergent Compositions" issued on 05/18/1971.
8. Wooden et al., U.S. Patent No. 3,733,277 entitled "Cleaning and Sanitizing Concentrate Containing Lemon-Lime Fragrance" issued on 5/15/1973.
9. Steltenkamp, U.S. Patent No. 3,988,432 entitled "Flavor and Fragrant Compositions" issued on 10/26/1976.
10. Juliano et al., U.S. Patent No. 4,014,995 entitled "Cosmetics Containing Finely Divided Oat Flour" issued on 3/29/1977.
11. Like et al., U.S. Patent No. 4,336,151 entitled "Disinfectant/Cleanser Compositions Exhibiting Reduced Eye Irritancy Potential" issued on 6/22/1982.
12. Like et al., U.S. Patent No. 4,336,152 entitled "Disinfectant/Cleanser Compositions Exhibiting Reduced Eye Irritancy Potential" issued on 6/22/1982.
13. Caskey et al., U.S. Patent No. 4,362,638 entitled "Gelled Laundry Pre-Spotter" issued on 12/7/1982.
14. Goffinet, U.S. Patent No. 4,414,128 entitled "Liquid Detergent Compositions" issued on 11/8/1983.

15. Brusky, U.S. Patent No. 4,438,009 entitled "Low Solvent Laundry Pre-Spotting Composition" issued on 3/20/1984.
16. Frazier, U.S. Patent No. 4,455,250 entitled "Stable Liquid Hard Surface Cleanser Composition Containing DGH and a Quaternary Germicide" issued on 6/19/1984.
17. Matta, U.S. Patent No. 4,511,488 entitled "D-Limonene Based Aqueous Cleaning Compositions" issued on 4/16/1985.
18. Jones, U.S. Patent No. 4,533,487 entitled "Process for Producing Blended D-Limonene and Uses of the Blended Product" issued on 8/6/1985.
19. Frazier, U.S. Patent No. 4,540,505 entitled "Disinfectant Spray Cleanser Containing Glycol Ethers" issued on 9/10/1985.
20. Smith et al., U.S. Patent No. 4,565,644 entitled "Floor Cleaning and Waxing Composition" issued on 1/21/1986.
21. Dellutri, U.S. Patent No. 4,620,937 entitled "All Purpose Cleaner Containing D-Limonene" issued on 11/4/1986.
22. Stoufer, U.S. Patent No. 4,704,225 (Re 33,210) entitled "Cleaning Composition of Terpene Hydrocarbon and a Coconut Oil Fatty Acid Alkanolamide Having Water Dispersed Therein" issued on 11/3/1987.
23. Frieser, U.S. Patent No. 4,790,951 entitled "Liquid All-Purpose Cleaning Preparations Containing Terpene and Hydrogenated Naphthalene as Fat Dissolving Agent" issued on 12/13/1988.
24. DeMatteo, U.S. Patent No. 4,859,359 entitled "Hard Surface Cleaning and Polishing Compositions" issued on 8/22/1989.
25. Lahanas et al., U.S. Patent No. 2004/0120795 entitled "Biliquid Foam Emulsions of Water and Hydrofluoroether as Cosmetic Carriers" published on 06/24/04.

B. Foreign Patents

1. EU Patent No. 0 080 749 entitled "Liquid Detergent Compositions" to The Procter & Gamble Company, inventor König issued on 04/16/86.
2. EU Patent Application No. 0 174 711 entitled "Biodegradable Emulsion for Removing Printing Ink from Printing Press Component Parts" to Ludwig, issued on 03/19/86.

C. General/Background References

1. Chemical Rubber Company, Handbook of Chemistry and Physics (CRC Press, 82nd ed., 2001).
2. Merck & Co., Inc., The Merck Index: An Encyclopedia of Chemicals, Drugs and Biologicals (11th ed., 1989).
3. Official Website of Florida Chemical Company, Inc. (2005), at <http://www.floridachemical.com/>.
4. Mitchell C. Schlossman, Chemistry and Manufacture of Cosmetics (M.C. Schlossman, ed., Allured Publishing Corp., 3d ed., 2002).
5. American Assn. Cereal Chemists, Oats Chemistry and Technology, (Francis H. Webster, ed., 1986).
6. CTFA (Cosmetic, Toiletry and Fragrance Association, Inc.), International Cosmetic Ingredient Dictionary and Handbook (2002).
7. CTFA, Cosmetic Ingredient Handbook (1st ed., 1988).
8. Julia F. Morton, Fruits of Warm Climates (1987).
9. Le-Nhung McLeland, American Chemical Society (ACS) Joint Board-Council Committee on Patents and Related Matters, What Every Chemist Should Know About Patents (L. McLeland, ed., 2002).
10. *Manual of Patent Examining Procedure, Appendix L, United States Code Title 35, Patents*, (Rev. 3, August 2005), at http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf.
11. R. J. Moore, Harry's Cosmeticology (J.B. Wilkinson ed., Chem. Pub. Co. 7th ed. 1982).

D. Other Materials

1. Two (2) memoranda re: Disperse Technology as used for making emulsions, produced and identified by Bates numbers BBW 004319- 004366.
2. Richard L. Coleman, *D-Limonene as a Degreasing Agent*, in The Citrus Industry, pp. 23-25 (Nov. 1975).
3. File History of U.S. Patent Application Ser. No. 07/786,804, including decision by Board of Patent Appeals and interferences dated April 15, 1997.

4. Physician's Desk Reference *for Nonprescription Drugs and Dietary Supplements*, pp. 665-666 (24th ed., 2003).
5. Physician's Desk Reference, p. 655 (43rd ed. 1989).
6. Pauline W. Thomas, Perfume Fashion History, *for* Fashion-Era.com (2006), at http://www.fashion-era.com/perfume_history.htm.
8. Florida Chemical Co., Inc., A Note About pH Measurement and d-Limonene, at http://www.floridachemical.com/dlimonene_phmeasurement.htm.

APPENDIX C

Table 1**Invalidity of Claim 6 of United States Patent No. 5,063,062 as Obvious in View of U.S. Patent No. 4,014,995 ("Juliano") and U.S. Patent No. 4,620,937 ("Dellutri")**

CLAIM 6 OF U.S. PATENT NO. 5,063,062	PRIOR ART
A skin cleaning composition for external use on human tissues, comprising:	<p>Dellutri discloses the use of citric oil as a cleaning agent:</p> <p>"This invention relates to cleaning agents, and more particularly to a cleaning agent having a citric oil composition for industrial cleaning, which can also be used as a hand cleaner as well as being an all purpose cleaner." (Dellutri, Col. 1, lines 6-10).</p> <p>Juliano discloses the use of oat flour in cleansing creams and lotions:</p> <p>"Cleansing creams and lotions not only offer bland effective removal of "make-ups," environmental residue, such as dust and dirt, but they offer an excellent method for lubricating and moisturizing dry skin. Oat flour can be incorporated into cleansing creams and lotions for the individual who finds this method of cleaning more acceptable than soap." (Juliano, Col. 2, lines 55-61).</p>
orange oil;	<p>Dellutri discloses the use of citric oil, and specifically its major component, d-limonene, as a cleaning agent:</p> <p>"A cleaning agent is provided which has a citric oil as its basic ingredient. The citric oil can be further combined with various other ingredients to enhance its usefulness as a cleaning agent. In a particular embodiment of the present invention, the citric oil is mainly distilled d-Limonene." (Dellutri, Col. 2, lines 10-16).</p> <p>The major portion of orange oil--over 90%-- is d-limonene. (<i>See generally</i>, Julia F. Morton, <i>Fruits of Warm Climates</i>).</p>
a pharmaceutically acceptable moisturizer for human skin;	<p>Dellutri discloses the use of Aloe Vera in cleaning compositions in combination with citric oil and d-limonene:</p> <p>"When the cleaning agent comprising the citric oils are combined with the water and the Aloe Vera juice, where possibly preselected amounts of surfactants, stabilizers and lanolin may also optionally be included as required, the cleaning agent can be effectively utilized as a hand cleaner." (Dellutri, Col. 3, lines 39-44).</p> <p>Aloe Vera is a well known moisturizer. (<i>See generally</i>, CTFA Cosmetic Dictionary and Handbook).</p> <p>Nearly every formulation example in Juliano utilizes at least one pharmaceutically acceptable moisturizer:</p>

	<p>“Moisturizing creams and lotions can be formulated with the oat flour, which functions along with other lubricants and emollients to impart a soft, smooth residual feel to the skin. Night creams and lotions can be compounded with the special oat flour. These systems can be formulated to achieve pH values which approximate those of normal skin.” (Juliano, Col. 1 line 67 – Col. 2, line 5; <i>See also</i>, Examples).</p> <p>“Oat flour can be incorporated into cleansing lotions and creams not only to impart a skin conditioning effect by virtue of its protein content, but it offers moisturizing properties due to the presence of lipids.” (Juliano, Col. 2, lines 51-54).</p>
<p>and an oat grain derivative product as an emulsifying agent;</p>	<p>Juliano utilizes an oat grain derivative as an emulsifying agent:</p> <p>“Oat flour can also contribute to the stability of these emulsions by virtue of effect on the apparent viscosity of these systems as well as solubility characteristics. Oat flour appears to have hydrophilic (water loving) as well as lipophilic groups which are postulated to give the flour value as an emulsifier.” (Juliano, Col. 3, lines 16-21).</p>
<p>wherein said composition has a pH within a range of 4.5 to 6.0 inclusively.</p>	<p>Dellutri discloses a composition with a pH 5.5:</p> <p>“The sample had approximately 19% of alcohol soluble solids (soap and surfactants), no alcohol insoluble solids, no free alkali, and no prohibited solids. It has a pH of 5.5 and a gelatinous consistency.” (Dellutri, Col. 3, lines 55-58).</p> <p>Juliano discloses a composition comprising a pH of 5.5:</p> <p>“These systems can be formulated to achieve pH values which approximate those of normal skin. Since the oat flour is compatible with various ingredients of cosmetic formulations, it is possible to design the products having pH values of approximately 5.5 (approximate skin pH)” (Juliano, Col. 2, lines 5-8).</p> <p>The motivation to combine the references lies in the fact that both references disclose improved hand cleaners.</p>

Invalidity of Claim 9 of United States Patent No. 5,063,062 as Obvious in View of U.S. Patent No. 4,014,995 ("Juliano") and U.S. Patent No. 4,620,937 ("Dellutri")

CLAIM 9 OF U.S. PATENT NO. 5,063,062	PRIOR ART
A cleaning compound for use on human skin comprising: forty-five percent (45%) or less by volume of orange oil; forty-five percent (45%) or less by volume of oatmeal; and a pharmaceutically acceptable moisturizer.	<p>Dellutri discloses a hand cleaner:</p> <p>"This invention relates to cleaning agents, and more particularly to a cleaning agent having a citric oil composition for industrial cleaning, which can also be used as a hand cleaner as well as being an all purpose cleaner." (Dellutri, Col. 1, lines 6-10).</p> <p>Juliano discloses a hand cleaner:</p> <p>"Cleansing creams and lotions not only offer bland effective removal of "make-ups," environmental residue, such as dust and dirt, but they offer an excellent method for lubricating and moisturizing dry skin. Oat flour can be incorporated into cleansing creams and lotions for the individual who finds this method of cleaning more acceptable than soap." (Juliano, Col. 2, lines 55-61).</p> <p>Dellutri discloses the use of citric oil, at less than 45% by volume:</p> <p>"1. A cleaning agent comprising: a liquid mixture of distilled, stabilized citric oil, vinegar and water; said distilled, stabilized citric oil being between 20% and 90% by volume of said mixture;" (Dellutri, Col. 4, lines 11-15).</p> <p>"The citric oil should be distilled and stabilized, and should be between 20% and 90% of the liquid volume of the cleaning agent mixture." (Dellutri, Col. 2, lines 19-23).</p> <p>Juliano utilizes oat flour:</p> <p>"The flour is used in cosmetic formulations in amounts of from about 1 to 20% or more of the formulation by weight." (Juliano, Col. 1, lines 37-40).</p> <p>Oat flour is ground oats of smaller particle size than oatmeal. Their physical properties are similar.</p> <p>Dellutri discloses the use of Aloe Vera in cleaning compositions in combination with citric oil and d-limonene:</p> <p>"When the cleaning agent comprising the citric oils are combined with the water and the Aloe Vera juice, where possibly preselected amounts of surfactants, stabilizers and lanolin may also optionally be included as required, the cleaning agent can be effectively utilized as a hand cleaner." (Dellutri, Col. 3, lines 39-44).</p> <p>Aloe Vera is a well known moisturizer. (<i>See generally</i>, CTFA Cosmetic</p>

	<p>Dictionary and Handbook).</p> <p>Nearly every formulation example in Juliano utilizes at least one pharmaceutically acceptable moisturizer:</p> <p>“Moisturizing creams and lotions can be formulated with the oat flour, which functions along with other lubricants and emollients to impart a soft, smooth residual feel to the skin. Night creams and lotions can be compounded with the special oat flour. These systems can be formulated to achieve pH values which approximate those of normal skin.” (Juliano, Col. 1 line 67 – Col. 2, line 5; See also, Examples).</p> <p>“Oat flour can be incorporated into cleansing lotions and creams not only to impart a skin conditioning effect by virtue of its protein content, but it offers moisturizing properties due to the presence of lipids.” (Juliano, Col. 2, lines 51-54).</p> <p>The motivation to combine the references lies in the fact that both references disclose improved hand cleaners.</p>
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Table 2**Invalidity of Claim 6 of United States Patent No. 5,063,062 as Obvious in View of U.S. Patent No. 4,620,937 (“Dellutri”) and U.S. Patent No. 2,436,818 (“Musher”)**

CLAIM 6 OF U.S. PATENT No. 5,063,062	PRIOR ART
A skin cleaning composition for external use on human tissues, comprising:	<p>Dellutri discloses a cleaning agent:</p> <p>“This invention relates to cleaning agents, and more particularly to a cleaning agent having a citric oil composition for industrial cleaning, which can also be used as a hand cleaner as well as being an all purpose cleaner.” (Dellutri, Col. 1, lines 6-10).</p> <p>Musher discloses a hand lotion and skin freshener:</p> <p>“The unusual oat fraction has also been found desirable in the preparation of hair lotions, skin fresheners and hair waving fluids.” (Musher, Col. 7, lines 59-61).</p>
orange oil;	<p>Dellutri discloses the use of citric oil, and specifically its major component, d-limonene, as a cleaning agent:</p> <p>“A cleaning agent is provided which has a citric oil as its basic ingredient. The citric oil can be further combined with various other ingredients to enhance its usefulness as a cleaning agent. In a particular embodiment of the present invention, the citric oil is mainly distilled d-Limonene.” (Dellutri, Col. 2, lines 10-16).</p> <p>The major portion of orange oil--over 90%-- is d-limonene. (<i>See generally</i>, Julia F. Morton, <i>Fruits of Warm Climates</i>).</p>
a pharmaceutically acceptable moisturizer for human skin;	<p>Dellutri discloses the use of Aloe Vera in cleaning compositions in combination with citric oil and d-limonene:</p> <p>“When the cleaning agent comprising the citric oils are combined with the water and the Aloe Vera juice, where possibly preselected amounts of surfactants, stabilizers and lanolin may also optionally be included as required, the cleaning agent can be effectively utilized as a hand cleaner.” (Dellutri, Col. 3, lines 39-44).</p> <p>Aloe Vera is a well known moisturizer. (<i>See generally</i>, CTFA Cosmetic Dictionary and Handbook).</p> <p>Musher discloses a hand lotion comprising lanolin:</p> <p>“8. A hand lotion comprising 5 parts by weight of glycerine, 0.75 part by</p>

	<p>weight of lanolin, 6 parts by weight of glycol stearate, 3 parts by weight of sorbitol syrup, 5 parts by weight of alcohol, 75.25 parts by weight of water and 5 parts by weight of the finely divided coarse fraction of dehulled oats, said finely divided coarse fraction being substantially free of those particles which will go through a 60 mesh screen when the dehulled oats are ground to a fineness that will permit 80% to 90% thereof to pass through a 60 mesh screen.” (Musher, Col. 11, lines 13-24).</p> <p>Lanolin is a well known moisturizer. (<i>See generally</i>, CTFA Cosmetic Ingredient Dictionary).</p>
<p>and an oat grain derivative product as an emulsifying agent;</p>	<p>Musher discusses the use of the oat fraction as an emulsifying agent:</p> <p>“Whereas normally these polyhydric alcohol esters “oil off” or come to the surface when added to any aqueous composition and thereby present a major difficulty when trying to obtain a uniform dispersion of the esters through the cosmetic, where the polyhydric alcohol ester is first combined with the special oat fraction of the present invention an unusual colloid appears to be formed whereby the polyhydric alcohol ester is uniformly dispersed therethrough without the oily composition coming to the surface and without “oiling off”. ” (Musher, Col. 9, lines 40-52).</p>
<p>wherein said composition has a pH within a range of 4.5 to 6.0 inclusively.</p>	<p>Dellutri discloses a composition with a pH 5.5:</p> <p>“The sample had approximately 19% of alcohol soluble solids (soap and surfactants), no alcohol insoluble solids, no free alkali, and no prohibited solids. It has a pH of 5.5 and a gelatinous consistency.” (Dellutri, Col. 3, lines 55-58).</p> <p>Musher discloses an oat grain derivative designed to be used in a composition with a pH between 2 and 10:</p> <p>“The desirable characteristics of these cosmetics preparations are given to the cosmetic by the unusual oat fraction of the present invention without respect to the pH of the cosmetic as the special oat fraction retains its desirable physical characteristics even within wide ranges of pH such as between pH 2 and pH 10.” (Musher, Col. 8, lines 25-31).</p> <p>The motivation to combine the references lies in the fact that both references describe skin cleaners.</p>

Invalidity of Claim 9 of United States Patent No. 5,063,062 as Obvious in View of U.S. Patent No. 4,620,937 ("Dellutri") and U.S. Patent No. 2,436,818 ("Musher")

CLAIM 9 OF U.S. PATENT NO. 5,063,062	PRIOR ART
A cleaning compound for use on human skin comprising: forty-five percent (45%) or less by volume of orange oil;	Dellutri discloses hand cleaner: "This invention relates to cleaning agents, and more particularly to a cleaning agent having a citric oil composition for industrial cleaning, which can also be used as a hand cleaner as well as being an all purpose cleaner." (Dellutri, Col. 1, lines 6-10). Musher discloses a hand lotion emulsion: "The unusual oat fraction has also been found desirable in the preparation of hair lotions, skin fresheners and hair waving fluids." (Musher, lines 59-61). Dellutri discloses the use of citric oil as a cleaning agent: "The citric oil should be distilled and stabilized, and should be between 20% and 90% of the liquid volume of the cleaning agent mixture." (Dellutri, Col. 2, lines 19-23). "A cleaning agent is provided which has a citric oil as its basic ingredient. The citric oil can be further combined with various other ingredients to enhance its usefulness as a cleaning agent. In a particular embodiment of the present invention, the citric oil is mainly distilled d-Limonene." (Dellutri, Col. 2, lines 10-16).
forty-five percent (45%) or less by volume of oatmeal;	Musher discloses a composition comprising less than 45% oatmeal: "The special oat fraction of the present invention is desirably used in a small proportion in the manufacture of cosmetic preparations such as in the amount of between 0.3% and 15% where an aqueous suspension such as a hand lotion is made, or in a larger amount, such as up to about 40% where a face mask is obtained, or in still larger amounts where a substantially dry cosmetic preparation such as a dentifrice or face powder is manufactured and where the most concentrated desirable characteristics of the special oat fraction of the present invention are to be utilized." (Musher, Col. 4, lines 45-57). Musher's oat fraction is a high protein fraction of oat grain. (Musher, Col. 2, lines 10-14).
and a pharmaceutically acceptable moisturizer.	Dellutri discloses the use of Aloe Vera in cleaning compositions in combination with citric oil and d-limonene: "When the cleaning agent comprising the citric oils are combined with the

water and the Aloe Vera juice, where possibly preselected amounts of surfactants, stabilizers and lanolin may also optionally be included as required, the cleaning agent can be effectively utilized as a hand cleaner.” (Dellutri, Col. 3, lines 39-44).

Aloe Vera is a well known moisturizer. (*See generally*, CTFA Cosmetic Dictionary and Handbook).

Musher discloses a hand lotion comprising lanolin:

“8. A hand lotion comprising 5 parts by weight of glycerine, 0.75 part by weight of lanolin, 6 parts by weight of glycol stearate, 3 parts by weight of sorbitol syrup, 5 parts by weight of alcohol, 75.25 parts by weight of water and 5 parts by weight of the finely divided coarse fraction of dehulled oats, said finely divided coarse fraction being substantially free of those particles which will go through a 60 mesh screen when the dehulled oats are ground to a fineness that will permit 80% to 90% thereof to pass through a 60 mesh screen.” (Musher, Col. 11, lines 13-24).

Lanolin is a well known moisturizer. (*See generally*, CTFA Cosmetic Ingredient Dictionary).

The motivation to combine the references lies in the fact that both references describe skin cleaners.

Table 3

Invalidity of Claim 6 of United States Patent No. 5,063,062 as Obvious in View of Coleman, "D-Limonene as a Degreasing Agent, The Citrus Industry, vol. 56, No. 11, Nov. 1975 and U.S. Patent No. 2,436,818 ("Musher")

CLAIM 6 OF U.S. PATENT No. 5,063,062	PRIOR ART
A skin cleaning composition for external use on human tissues, comprising:	<p>Coleman discloses a hand cleaner:</p> <p>"The potential of d-limonene (the principal component in orange oil) as a degreasing agent was explored. D-limonene was used in three formulations: a gel-type hand cleaner, a lotion-type hand cleaner and a gel type engine cleaner." (Coleman, pg. 23).</p> <p>Musher discloses a hand lotion and skin freshener:</p> <p>"The unusual oat fraction has also been found desirable in the preparation of hair lotions, skin fresheners and hair waving fluids." (Musher, lines 59-61). The motivation to combine Coleman and Musher is self-evident. Both references disclose compositions which are useful as hand cleaners and conditioners.</p>
orange oil;	<p>Coleman discusses the use of citrus oil:</p> <p>"Distilled citrus oil (~ 94% d-limonene) was obtained from a chemical supplier and used in the following formulations." (Coleman, pg. 24).</p>
a pharmaceutically acceptable moisturizer for human skin;	<p>Coleman uses lanolin, a well known moisturizer, in a Lotion-Type hand cleaner:</p> <p><u>"Lotion-Type hand cleaner"</u></p> <p>Solution A: 300-450 g d-limonene 30 g lanolin</p> <p>Solution B: 25 g Arlacel 40 75 g Tween 40 15 g Arlacel 60 85 g Tween 60" (Coleman, pg 24).</p> <p>Musher discloses a hand lotion comprising lanolin:</p> <p>"8. A hand lotion comprising 5 parts by weight of glycerine, 0.75 part by weight of lanolin, 6 parts by weight of glycol stearate, 3 parts by weight of sorbitol syrup, 5 parts by weight of alcohol, 75.25 parts by weight of water and 5 parts by weight of the finely divided coarse fraction of dehulled oats, said finely divided coarse fraction being substantially free of those particles which will go through a 60 mesh screen when the dehulled oats are ground to</p>

	<p>a fineness that will permit 80% to 90% thereof to pass through a 60 mesh screen.” (Musher, Col. 11, lines 13-24).</p> <p>Lanolin is a well known moisturizer. (<i>See generally</i>, CTFA Cosmetic Ingredient Dictionary).</p>
and an oat grain derivative product as an emulsifying agent;	<p>Musher discusses the use of an oat fraction as an emulsifying agent to prevent the “oiling off” and to maintain a uniform dispersion of polyhydric alcohol esters.</p> <p>“Whereas normally these polyhydric alcohol esters “oil off” or come to the surface when added to any aqueous composition and thereby present a major difficulty when trying to obtain a uniform dispersion of the esters through the cosmetic, where the polyhydric alcohol ester is first combined with the special oat fraction of the present invention an unusual colloid appears to be formed whereby the polyhydric alcohol ester is uniformly dispersed therethrough without the oily composition coming to the surface and without “oiling off.”” (Musher, Col. 9, lines 40-52).</p>
wherein said composition has a pH within a range of 4.5 to 6.0 inclusively.	<p>Musher discloses that the oat fraction is designed to be used in a composition with a pH between 2 and 10:</p> <p>“The desirable characteristics of these cosmetics preparations are given to the cosmetic by the unusual oat fraction of the present invention without respect to the pH of the cosmetic as the special oat fraction retains its desirable physical characteristics even within wide ranges of pH such as between pH 2 and pH 10.” (Musher, Col. 8, lines 25-31).</p> <p>The motivation to combine Coleman and Musher lies in the fact that both references disclose hand cleaners.</p>

Invalidity of Claim 9 of United States Patent No. 5,063,062 as Obvious in View of Coleman, “D-Limonene as a Degreasing Agent, The Citrus Industry, vol. 56, No. 11, Nov. 1975 and U.S. Patent No. 2,436,818 (“Musher”)

CLAIM 9 OF U.S. PATENT No. 5,063,062	PRIOR ART
A cleaning compound for use on human skin comprising:	<p>Coleman discloses a hand cleaner:</p> <p>“The potential of d-limonene (the principal component in orange oil) as a degreasing agent was explored. D-limonene was used in three formulations: a gel-type hand cleaner, a lotion-type hand cleaner and a gel type engine cleaner.” (Coleman, pg. 23).</p> <p>Musher discloses a hand lotion and skin freshener:</p>

	<p>“The unusual oat fraction has also been found desirable in the preparation of hair lotions, skin fresheners and hair waving fluids.” (Musher, lines 59-61).</p>
forty-five percent (45%) or less by volume of orange oil;	<p>Coleman discloses a Lotion Type hand cleaner containing from about 27-41% by volume orange oil. (Coleman, pg. 24).</p>
forty-five percent (45%) or less by volume of oatmeal;	<p>Musher discloses a composition comprising less than 45% oatmeal:</p> <p>“The special oat fraction of the present invention is desirably used in a small proportion in the manufacture of cosmetic preparations such as in the amount of between 0.3% and 15% where an aqueous suspension such as a hand lotion is made, or in a larger amount, such as up to about 40% where a face mask is obtained, or in still larger amounts where a substantially dry cosmetic preparation such as a dentrifice or face powder is manufactured and where the most concentrated desirable characteristics of the special oat fraction of the present invention are to be utilized.” (Musher, Col. 4, lines 45-57).</p> <p>Musher’s oat fraction is a high protein fraction of oat grain.</p>
and a pharmaceutically acceptable moisturizer.	<p>Coleman uses lanolin, a well known moisturizer, in a Lotion-Type hand cleaner:</p> <p><u>“Lotion-Type hand cleaner</u></p> <p>Solution A: 300-450 g d-limonene 30 g lanolin</p> <p>Solution B: 25 g Arlacel 40 75 g Tween 40 15 g Arlacel 60 85 g Tween 60” (Coleman, pg 24).</p> <p>Musher discloses a hand lotion comprising lanolin:</p> <p>“8. A hand lotion comprising 5 parts by weight of glycerine, 0.75 part by weight of lanolin, 6 parts by weight of glycol stearate, 3 parts by weight of sorbitol syrup, 5 parts by weight of alcohol, 75.25 parts by weight of water and 5 parts by weight of the finely divided coarse fraction of dehulled oats, said finely divided coarse fraction being substantially free of those particles which will go through a 60 mesh screen when the dehulled oats are ground to a fineness that will permit 80% to 90% thereof to pass through a 60 mesh screen.” (Musher, Col. 11, lines 13-24).</p> <p>Lanolin is a well known moisturizer. (See generally, CTFA Cosmetic Ingredient Dictionary).</p> <p>The motivation to combine Coleman and Musher lies in the fact that both references disclose hand cleaners.</p>

Table 4

Invalidity of Claim 6 of United States Patent No. 5,063,062 as Obvious in View of Coleman, "D-Limonene as a Degreasing Agent, The Citrus Industry, vol. 56, No. 11, Nov. 1975 and U.S. Patent No. 4,014,995 ("Juliano")

CLAIM 6 OF U.S. PATENT No. 5,063,062	PRIOR ART
A skin cleaning composition for external use on human tissues, comprising:	<p>Coleman discloses a hand cleaner:</p> <p>"The potential of d-limonene (the principal component in orange oil) as a degreasing agent was explored. D-limonene was used in three formulations: a gel-type hand cleaner, a lotion-type hand cleaner and a gel type engine cleaner." (Coleman, pg. 23).</p> <p>Juliano discloses cleansing creams and lotions:</p> <p>"Cleansing creams and lotions not only offer bland effective removal of "make-ups," environmental residue, such as dust and dirt, but they offer an excellent method for lubricating and moisturizing dry skin. Oat flour can be incorporated into cleansing creams and lotions for the individual who finds this method of cleaning more acceptable than soap." (Juliano, Col. 2, lines 55-61).</p>
orange oil;	<p>Coleman discusses the use of citrus oil:</p> <p>"Distilled citrus oil (~ 94% d-limonene) was obtained from a chemical supplier and used in the following formulations." (Coleman, pg. 24).</p>
a pharmaceutically acceptable moisturizer for human skin;	<p>Coleman uses lanolin, a well known moisturizer, in a Lotion-Type hand cleaner:</p> <p><u>"Lotion-Type hand cleaner</u></p> <p>Solution A: 300-450 g d-limonene 30 g lanolin</p> <p>Solution B: 25 g Arlacel 40 75 g Tween 40 15 g Arlacel 60 85 g Tween 60" (Coleman, pg 24).</p> <p>Nearly every formulation example in Juliano utilizes at least one pharmaceutically acceptable moisturizer:</p> <p>"Moisturizing creams and lotions can be formulated with the oat flour, which functions along with other lubricants and emollients to impart a soft, smooth residual feel to the skin. Night creams and lotions can be compounded with the special oat flour. These systems can be formulated to achieve pH values which approximate those of normal skin." (Juliano, Col. 1 line 67 – Col. 2,</p>

	<p>line 5; See also, Examples).</p> <p>“Oat flour can be incorporated into cleansing lotions and creams not only to impart a skin conditioning effect by virtue of its protein content, but it offers moisturizing properties due to the presence of lipids.” (Juliano, Col. 2, lines 51-54).</p>
and an oat grain derivative product as an emulsifying agent;	<p>Juliano utilizes oat flour as an emulsifying agent:</p> <p>“Oat flour can also contribute to the stability of these emulsions by virtue of effect on the apparent viscosity of these systems as well as solubility characteristics. Oat flour appears to have hydrophilic (water loving) as well as lipophilic groups which are postulated to give the flour value as an emulsifier.” (Juliano, Col. 3, lines 16-21).</p>
wherein said composition has a pH within a range of 4.5 to 6.0 inclusively.	<p>Juliano discloses a composition comprising a pH of 5.5:</p> <p>“These systems can be formulated to achieve pH values which approximate those of normal skin. Since the oat flour is compatible with various ingredients of cosmetic formulations, it is possible to design the products having pH values of approximately 5.5 (approximate skin pH)” (Juliano, Col. 2, lines 5-8).</p> <p>The motivation to combine Juliano and Coleman lies in the fact that both references disclose hand cleaners.</p>

Invalidity of Claim 9 of United States Patent No. 5,063,062 as Obvious in View of Coleman, “D-Limonene as a Degreasing Agent, The Citrus Industry, vol. 56, No. 11, Nov. 1975 and U.S. Patent No. 4,014,995 (“Juliano”)

CLAIM 9 OF U.S. PATENT No. 5,063,062	PRIOR ART
A cleaning compound for use on human skin comprising:	<p>Coleman discloses a citrus oil hand cleaner:</p> <p>“The potential of d-limonene (the principal component in orange oil) as a degreasing agent was explored. D-limonene was used in three formulations: a gel-type hand cleaner, a lotion-type hand cleaner and a gel type engine cleaner.” (Coleman, pg. 23).</p> <p>Juliano discloses the use of oat flour in cleansing creams and lotions:</p> <p>“Cleansing creams and lotions not only offer bland effective removal of “make-ups,” environmental residue, such as dust and dirt, but they offer an excellent method for lubricating and moisturizing dry skin. Oat flour can be incorporated into cleansing creams and lotions for the individual who finds this method of cleaning more acceptable than soap.” (Juliano, Col. 2, lines</p>

	55-61).
forty-five percent (45%) or less by volume of orange oil;	Coleman discloses a Lotion Type hand cleaner containing from about 27-41% by volume orange oil. (Coleman, pg. 24).
forty-five percent (45%) or less by volume of oatmeal;	Juliano utilizes oat flour: “The flour is used in cosmetic formulations in amounts of from about 1 to 20% or more of the formulation by weight.” (Juliano, Col. 1, lines 37-40). Oat flour is ground oats of smaller particle size than oatmeal. Their physical properties are similar.
and a pharmaceutically acceptable moisturizer.	Coleman uses lanolin, a well known moisturizer, in a Lotion-Type hand cleaner: <u>“Lotion-Type hand cleaner</u> Solution A: 300-450 g d-limonene 30 g lanolin Solution B: 25 g Arlacel 40 75 g Tween 40 15 g Arlacel 60 85 g Tween 60” (Coleman, pg 24). Nearly every formulation example in Juliano utilizes at least one pharmaceutically acceptable moisturizer: Moisturizing creams and lotions can be formulated with the oat flour, which functions along with other lubricants and emollients to impart a soft, smooth residual feel to the skin. Night creams and lotions can be compounded with the special oat flour. These systems can be formulated to achieve pH values which approximate those of normal skin.” (Juliano, Col. 1 line 67 – Col. 2, line 5; See also, Examples). “Oat flour can be incorporated into cleansing lotions and creams not only to impart a skin conditioning effect by virtue of its protein content, but it offers moisturizing properties due to the presence of lipids.” (Juliano, Col. 2, lines 51-54).

APPENDIX D-1

Appendix D-1
BBW - d-Limonene Cleanser Formulas

Formula #1

From Example XIX (US '062); NB Ref CPD8-10, 12-21-05

Objective: To evaluate emulsifying ability/stability of oatmeal/limonene combinations.

Materials

<u>INGREDIENTS</u>	<u>SUPPLIER</u>	<u>%</u>
PART A		
Aloe Vera (1:10)	Pure World	0.775
RO Water	laboratory	6.975
Jojoba Oil Golden	Desert Whale Jojoba Co., Inc.	7.750
Glycerin	PCI Scientific	4.500
Safflower Oil	Hain Celestial Group, Inc.	0.500
PART B		
d-Limonene	Florida Chemical Co., Inc.	40.500
PART C		
Oatmeal [†]	Beacon CMP Corp.	<u>39.000</u>
		100.000

Method**Formula #1A –**

The initial mixture is half oats and half water (per US '062). The water was heated to boiling, the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. The water was QS'ed,[‡] the Part C was mixed until uniform and the formula amount was weighed and added to the batch.

Formula #1B –

The oats mixture is 33.3% oats and 66.7% water. The water was heated to boiling, the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. The water was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch.

Formula #1C –

The oats mixture is 10% oats and 90% water. The water was heated to boiling, the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. The water

[†] The oatmeal component is a mixture of water and processed rolled oats (per US '062).

[‡] Quantity Sufficient

was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch.

Formula #1D –

The oats mixture is 5% oats and 95% water. The water was heated to boiling, the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. The water was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch.

Observations (24 hours after mixing)

Formula #1A –

Pasty, opaque oatmeal looking product with a separated layer on top. A sample of the top layer did not mix with water. The top layer is opaque, not clear.

Formula #1B –

Pasty, opaque oatmeal looking product with a separated layer. A sample of the separated liquid did not mix with water. The separated liquid is opaque, not clear. The oatmeal formed a ball in the center of the liquid. The product was not uniform

Formula #1C –

Fluid, flowing, viscous opaque oatmeal looking product with a separated layer of about 50% volume on top. A sample of the top layer did not mix with water. The top layer is light yellow in color and hazy/translucent, not clear.

Formula #1D –

The product is very fluid and composed of three layers. The bottom is an opaque, low viscosity liquid. The middle layer is a low viscosity opaque curdled, oatmeal-like material. The top layer is a low viscosity, light yellow very slightly hazy liquid. A sample of the top layer did not mix with water.

Conclusions

See Conclusions in Appendix D-2.

APPENDIX D-2

Appendix D-2
Orange Oil Cleanser Formulas

Formula #2

From Example XIX (US '062); NB Ref CPD8-25, 1-30-06

Objective: To evaluate emulsifying ability/stability of oatmeal/orange oil combinations.

Materials

<u>INGREDIENTS</u>	<u>SUPPLIER</u>	<u>%</u>
<u>PART A</u>		
Aloe Vera (1:10)	Pure World	0.775
RO Water	laboratory	6.975
Jojoba Oil Golden	Desert Whale Jojoba Co., Inc.	7.750
Glycerin	PCI Scientific	4.500
Safflower Oil	Hain Celestial Group, Inc.	0.500
<u>PART B</u>		
Orange Oil	Florida Chemical Co., Inc.	40.500
<u>PART C</u>		
Oatmeal [§]	The Quaker Oats Co.	39.000
		100.000

Method

Formula #2A –

The initial mixture is half oats and half water (per Example XIX). The water was heated to boiling; the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. When cooled, the water was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch with mixing and mixed until uniform.

Formula #2B –

The oats mixture is 33.3% oats and 66.7% water. The water was heated to boiling; the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. When cool, the water was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch with mixing and was mixed until uniform.

Formula #2C –

The oats mixture is 10% oats and 90% water. The water was heated to boiling; the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. When cool,

[§] The oatmeal component is a mixture of water and processed rolled oats (per US '062).

the water was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch with mixing and mixed until uniform.

Formula #2D –

The oats mixture is 5% oats and 95% water. The water was heated to boiling; the oats were added, mixed until uniform, then covered and allowed to cool to room temperature. When cool, the water was QS'ed, the Part C was mixed until uniform and the formula amount was weighed and added to the batch with mixing and mixed until uniform.

Observations (24 hours after mixing)

Formula #2A –

has a pasty, opaque oatmeal looking product in the center of the container surrounded by a low viscosity separated orange liquid. A sample of the orange liquid was clear and did not mix with water.

Formula #2B –

has a pasty, soft, opaque oatmeal looking product in the center of the container surrounded by a low viscosity separated orange liquid. A sample of the orange liquid was hazy and did not mix with water.

Formula #2C –

was a fluid, free flowing, liquid product with three separated layers. The bottom layer is hazy/clear, light in color and appears to be water. It occupies about 33% of the total formula volume. The center layer occupies about 60% of the formula volume - it is an opaque, grainy looking, orange, free flowing liquid. The top layer is a clear/hazy orange liquid and occupies about 10% of the formula volume. A sample of the top layer did not mix with water. A sample of the center layer mixed with water to produce a hazy solution/dispersion with an oily layer that smelled of orange oil on top. A sample of the bottom layer mixed easily with water making a hazy solution/dispersion that smelled like orange oil.

Formula #2D –

was a fluid, free flowing, liquid product with three separated layers each occupying about 1/3 of the formula volume. The bottom layer is hazy/clear, light in color and appears to be water. The center layer is an opaque, grainy looking, orange colored, free flowing liquid. The top layer is a clear/hazy orange liquid. A sample of the top layer did not mix with water. A sample of the center layer mixed with water to produce a hazy solution/dispersion with an oily layer that smelled of orange oil on top. A sample of the bottom layer mixed easily with water making a hazy solution/dispersion that smelled like orange oil.

Conclusions

1. The first two products (Formula #2A and Formula #2B) do not form stable emulsions (they separate after standing for 24 hours), but, when shaken or mixed vigorously, they become uniform and are slow to separate. These two products appear to behave

similarly to the analogous Formula #1A and Formula #1B that were made with d-limonene in place of orange oil (see Attachment E). After one month of room temperature storage these two formulas will make emulsified (or one phase appearing) products that do show separation after 24 hours standing at room temperature.

2. The second two products (Formula #2C and Formula #2D) do not form stable emulsions and separate quickly (within one hour) into several layers with a significant oily liquid layer on top. The behavior of the analogous formulas made with d-limonene (Formula #1C and Formula #1D from Attachment E) is similar and these formulas show significant separation within one hour after vigorous mixing.
3. In my judgment, Formula #1A, Formula #1B, Formula #2A and Formula #2B can be considered to be emulsions although they are not particularly stable.
4. In my judgment, Formula #1C, Formula #1D, Formula #2C and Formula #2D can not be considered to be emulsions.
5. Therefore, in my judgment, there is a minimum amount of Oatmeal needed to make an acceptable emulsion with Orange Oil. That minimum is somewhere between the 33% Oatmeal Formula #2B (containing ~13% Rolled Oats and ~26% water) and the 10% Oatmeal Formula #2C (containing ~4% Rolled Oats and ~35% water).

APPENDIX D-3

Appendix D-3
BBW - Evaluation of Oat Extracts as Emulsifiers

Test Procedure/Objective: To evaluate oat extracts as emulsifiers

Materials

Extracts Tested	Product #	Lot#
Active Concepts Oat Hydrolysate	20619	5384
Active Concepts Quaternized Oat	20706	SN050822-4
Active Concepts Oat Amino Acids	20633	SN051104-2
Active Concepts ABS Oat Extract	10243	SN051219-6
Active Concepts Foaming Oat	20613	SN050322-8
Active Concepts Oat Protein Powder	22005	SN030410-2
Active Concepts Colloidal Oat Flour	22003	SN051219-5
Actiphyte of Oat Flour Lipo S	324060-15	S33531A
Actiphyte of Oat Bran	334913-11	S24288A
Actiphyte of Oat	344360-11	S35651A
Actiphyte of Oat Lipo S	344360-15	S33497B
Symcalmin	143535	10
Avena Lipid (Drago Lipid)	206889	3J2
Drago Calm (2/060910)	674463	5J4
Proteol OAT	N/A	0501300018
Solu-Oat EN-20 (Hydrolyzed oat protein)	01895	L05-428

The following formula was prepared for each extract:

INGREDIENTS	%
RO Water	87.90
Kathon CG	0.10
Test Oat Extract	10.00
d-Limonene	<u>2.00</u>
	100.00

Method

For each extract - the formula ingredients were weighed into a two (2) fl oz glass bottle, shaken well to mix (for at least one minute) and allowed to stand undisturbed overnight and then evaluated.

Results

Test Extracts	Observations
1) Active Concepts Oat Hydrolysate	Separation - oil layer on top - formed individual oil droplets when gently shaken
2) Active Concepts Quaternized Oat	Separation - oil layer on top - formed individual oil droplets when gently shaken
3) Active Concepts Oat Amino Acids	Separation - oil layer on top - formed individual oil droplets when gently shaken - bottom water layer was hazy
4) Actiphyte of Oat Flour Lipo S	Separation - oil layer on top - formed individual oil droplets when gently shaken - oil layer was larger than that seen in 1)
5) Actiphyte of Oat Bran	Separation - oil layer on top - formed individual oil droplets when gently shaken
6) Actiphyte of Oat	Separation - oil layer on top - formed individual oil droplets when gently shaken
7) Actiphyte of Oat Lipo S	Separation - oil layer on top - formed individual oil droplets when gently shaken - oil layer was larger than that seen in 1)
8) Avena Lipid (Drago Lipid)	Separation - oil layer on top - formed individual oil droplets when gently shaken - oil layer was larger than that seen in 1) and was light yellow in color and hazy
9) Drago Calm (2/060910)	Separation - oil layer on top - formed individual oil droplets when gently shaken - bottom water layer was hazy
10) Solu-Oat EN-20	Separation - oil layer on top - formed individual oil droplets when gently shaken - bottom water layer was light straw colored and slightly hazy
11) * Proteol OAT	Hazy/opaque layer on top that dispersed in the water layer when shaken (creaming)
12) *Active Concepts ABS Oat Extract	Hazy/opaque layer on top that dispersed in the water layer when shaken (creaming)
13) *Active Concepts Foaming Oat	Hazy/opaque layer on top that dispersed in the water layer when shaken (creaming) - water layer was light yellow in color

14) *Active Concepts Oat Protein Powder Thick (viscous), uniform opaque liquid

15) *Active Concepts Colloidal Oat Flour Thick (viscous), uniform opaque liquid

16) * Symcalmin Solid appearing flocculent material seen on bottom and floating throughout the bottom water layer

* The last six test formulas are considered to be emulsions.

COMMENTS

Regarding Test Extract 11

Proteol OAT is sodium lauroyl oat amino acids - the product of the Schotten-Baumann reaction of lauroyl acid chloride and sodium oat amino acids. This reaction makes an anionic surfactant that can be used as a foaming detergent and an emulsifier. It is a commonly employed method to produce a chemical derivative of an amino acid or protein that can be used as a surfactant. Sodium N-lauroyl sarcosinate (Gardol®) is a well known example of this type of surfactant. This product is not considered to be an extract because it has been chemically modified with the intention of creating a surfactant.

Regarding Test Extract 12

AC - ABS Oat Extract does have some emulsifying ability at 10% concentration and it is an extract.

Regarding Test Extract 13

AC Foaming Oat is sodium cocoyl hydrolyzed oat protein and, for the same reasons presented in Comments 11) above, is not considered to be an extract because it has been chemically modified with the intention of creating a surfactant.

Regarding Test Extract 14

AC Oat Protein Powder is hydrolyzed oat protein and is an emulsifier at 10% concentration.

Regarding Test Extract 15

AC Colloidal Oat Flour is oat kernel flour and is an emulsifier at 10% concentration.

Regarding Test Extract 16

SymCalmin is a 5% solution of a synthetic Avenanthramide (Dihydroavenanthramide D) in butylene glycol and pentylene glycol and is an emulsifier at 10% concentration. It is a synthetic product - not an extract.

ADDITIONAL TESTS

Objective: Items 12, 14 and 15 will be evaluated for their emulsifying properties at 5% and 1%.

Materials

As set forth above and below.

Methods

As set forth above and below.

Results

Test Extracts	Observations
Item 12 retest - AC - ABS Oat Extract @ 5%	Hazy/opaque layer on top that dispersed in the water layer when shaken (creaming) - but with oil separation on top (from the cream) - slight, but poor emulsifier
Item 12 retest - AC - ABS Oat Extract @ 1%	Hazy/opaque layer on top that dispersed in the water layer when shaken (creaming) - but with a lot of oil (d-limonene) separation on top (from the cream) - very little cream - not a stable emulsion
Item 14 retest - AC Oat Protein Powder @ 5%	Hazy/opaque bottom layer with very dense opaque layer at the bottom (~ 1/2 of bottom layer) and with opaque (cream) layer on top - but with a layer of separated oil (d-limonene) that forms visible droplets (not an emulsion) when gently shaken - not a stable emulsion
Item 14 retest - AC Oat Protein Powder @ 1%	Hazy/opaque bottom layer with very dense, small opaque layer at the bottom (~ 1/8" on the bottom) and with opaque (cream) layer on top - but with a layer of separated oil (d-limonene) that forms visible droplets (not an emulsion) when gently shaken - not a stable emulsion
Item 15 retest - AC Colloidal Oat Flour @ 5%	Hazy/opaque bottom layer with very dense opaque layer at the bottom (~ 1/2 of bottom layer) and with opaque (cream) layer on top - but with a layer of separated oil (d-limonene) that forms visible droplets (not an emulsion) when gently shaken - not a stable emulsion

Item 15 retest - AC Colloidal Oat Flour @ 1%

Hazy/opaque bottom layer with very dense, small opaque layer at the bottom (~ 1/8" on the bottom) and with opaque (cream) layer on top - but with a layer of separated oil (d-limonene) that forms visible droplets (not an emulsion) when gently shaken - not a stable emulsion

CONCLUSIONS

1. Two of the "extracts" tested are not considered to be true extracts because they are intentionally chemically modified to produce surfactants.
2. One of the "extracts" is a synthetic material. The original compound was found in oats. It is manufactured and sold as an active anti-itch and anti-irritant ingredient. This material is not considered to be an extract.
3. One of the extracts (AC - ABS Oat Extract) showed stable emulsifying properties of d-limonene at 5%.
4. Two extracts (AC Oat Protein Powder and AC Colloidal Oat Flour) showed emulsifying properties of d-limonene at 10%, but not at 5%.
5. The remaining ten (10) extracts are not emulsifiers of d-limonene at 10% w/w concentration.

APPENDIX D-4

Appendix D-4
Evaluation of Oat Extracts as Orange Oil Emulsifiers

Test Procedure/Objective: To evaluate oat extracts as orange oil emulsifiers

Materials

<u>Extracts Tested</u>	<u>Product #</u>	<u>Lot#</u>
Unitanical Oat WS	R10655	643729A
Unitanical Oat	R10605	484459
Unitanical Oat IN	R10632	484460
Actiphyte of Oat	344360-11	S35651A
Proteol OAT	N/A	0501300018
Solu-Oat EN-20 (Hydrolyzed oat protein)	01895	L05-428
Active Concepts Oat Protein Powder	22005	SN030410-2

Test Procedure/Method

The following formula was prepared for each extract:

<u>INGREDIENTS</u>	<u>%</u>
RO Water	87.90
Kathon CG	0.10
Test Oat Extract	10.00
Orange Oil	<u>2.00</u>
	100.00

For each extract - the formula ingredients were weighed into a two (2) fl oz glass bottle, shaken well to mix (for at least one minute) and allowed to stand undisturbed for 24 hours and then evaluated.

RESULTS

<u>Test Extracts</u>	<u>Observations</u>
1) Unitanical WS	Separation - oil layer on top - formed individual oil droplets when gently shaken, clear/hazy water on bottom. No Emulsion.
2) Unitanical Oats*	Separation - Large (~25% by volume) cream layer on top with cloudy water layer on the bottom. The cream disperses making an opaque emulsion when shaken. Not a stable emulsion.
3) Unitanical Oat IN	Separation - oil layer on top - formed individual oil droplets when gently shaken, clear/hazy water on bottom. No Emulsion.

4) Actiphyte of Oat	Separation - oil layer on top - formed individual oil droplets when gently shaken, clear/hazy water on bottom. No Emulsion.
5) Proteol OAT* Tested 1-6-06 CPD8-19	Separation - Small orange colored cream layer on top with a clear water layer on the bottom. The cream disperses making an opaque emulsion when shaken. Not a stable emulsion.
6) Solu-Oat EN-20 Tested 1-6-06 CPD8-19	Separation - oil layer on top - formed individual oil droplets when gently shaken, clear/hazy range/yellow colored water on bottom. No Emulsion.
7) AC Oat Protein Powder* (5%)	Separation - Small orange colored cream layer on top with a cloudy/opaque water layer on the bottom with ~ 50% white flocculent material as a precipitate. The cream disperses making an opaque emulsion when shaken. Not a stable emulsion.
8) AC Oat Protein Powder (1%)	Separation - orange oil layer on top - formed individual oil droplets when gently shaken. The lower water layer was cloudy/opaque and has a precipitate layer that is ~ 10% of the water volume. The orange oil layer dispersed easily when the bottle was shaken to make a cloudy emulsion that separated quickly (within one minute). No Emulsion.

* These three products make temporary (non stable) emulsions with orange oil at the specified concentration. They may contribute to emulsion stability if another emulsifier is present.

Conclusions

1. Actiphyte of Oat, AC Oat Protein Powder, Proteol OAT and Solu-Oat EN-20 were tested previously using d-limonene as the oil phase in place of orange oil (Attachment F). In that test, Actiphyte Oat at 10% concentration and Solu-Oat EN-20 at 10% concentration were not emulsifiers of limonene and they are also not emulsifiers of orange oil in this test.
2. Proteol OAT at 10% concentration was found to make a poor emulsion with limonene that creamed quickly (Attachment F). The same results were found with orange oil. In addition, Proteol OAT is a chemical modification of oat amino acids that is intended to produce a mild, high foaming anionic surfactant. As such, it is a chemical derivative and not an extract.
3. AC Oat Protein Powder was previously tested (Attachment F) and found to be an emulsifier of limonene at 10%. It was not retested at 10% with orange oil. Rather it was tested at 5% and 1% concentrations as it had also been with limonene. The results with orange oil were the same as with limonene and AC Oat Protein Powder was found not to be an emulsifier of either limonene or orange oil at 1% and 5%, although it may be at 10%.

So, it is not an emulsifier of orange oil or limonene at concentrations less than 5%.

4. The Unitanical Oat extracts were tested at 10% concentration and none of them were found to be emulsifiers of orange oil.

APPENDIX D-5

Appendix D-5
Comparison of Orange Oil and d-limonene Formulas for Cleaning

Objective

To compare the cleaning ability of various concentrations of Orange Oil to the same concentrations of d-limonene in an oatmeal formulation that is taken from Example V of U.S. Patent No. 5,063,062 ("the '062 patent").

Materials and Methods

Formulas

<u>Ingredients</u>	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>E</u>
Orange Oil	36.5	22.0	12.0	7.0	3.5
Moisturizer Blend	35.5	35.5	35.5	35.5	35.5
Oatmeal	28.0	28.0	28.0	28.0	28.0

A = ~ 36.5 % v/v orange oil; B = ~ 25.7% v/v orange oil (25%); C = ~15.9% orange oil (15%); D = ~ 9.9 % v/v orange oil (10%), E = ~ 5.2 % v/v orange oil (5%)

NOTE 1 : Orange Oil is measured in cc's per US '062 and the moisturizer and oatmeal are weighed in grams per the '062 patent.

NOTE 2 : Formulas A and B were NOT homogenous - both showed separation of a clear liquid on top that appeared to be orange oil. The other formulas did not show separation

<u>Ingredients</u>	<u>F</u>	<u>G</u>	<u>H</u>	<u>J</u>	<u>L</u>
d-limonene	36.5	22.0	12.0	7.0	3.5
Moisturizer Blend	35.5	35.5	35.5	35.5	35.5
Oatmeal	28.0	28.0	28.0	28.0	28.0

F = ~ 36.5 % v/v d-limonene; G = ~ 25.7% v/v d-limonene (25%); H = ~15.9% d-limonene (15%); J = ~ 9.9 % v/v d-limonene (10%), L = ~ 5.2 % v/v d-limonene (5%)

NOTE 3: d-limonene is measured in cc's per US '062 and the moisturizer and oatmeal are weighed in grams per US '062

NOTE 4 : Formulas F and G were NOT homogenous - both showed separation of a clear liquid on top that appeared to be d-limonene. The other formulas did not show separation

Procedure

Eleven 4X4 inch square light grey ceramic tiles were coated with three (3) bands of different materials to be tested for remove-ability by the Example V formulas :

Top Band	Tangerine High Gloss Enamel Paint (Frisch Paints) - solvent based
Middle Band	Polyurethane Foaming Insulation (True Value)
Bottom Band	Revlon Age Defying Makeup # 12 Rich Tan

Eleven 4X4 inch square light grey ceramic tiles were coated with three (3) bands of different materials to be tested for remove-ability by the Example V formulas :

Top Band	Sears Best Easy Living vinyl acrylic latex semi gloss - water based paint
Middle Band	Black Jack Roof Cement Asphalt roof patch (Gibson Homens)
Bottom Band	Wet and Wild Lipstick # 533C (Markwins Beauty Products)

The tiles were allowed to dry for twenty four hours (24) before use. The tiles were labeled -front and back - to identify the materials being applied.

Five (5) cc's (mls) of one of the Orange Oil formulas was applied in a continuous ribbon as extruded from a syringe to a designated section of a tile. The formula was applied at right angles to the three (3) bands of Test material on the tile. The formula was distributed as evenly as possible and in intimate contact with each test material to be removed. The comparison percentage d-limonene formula was applied to the same tile in the same manner to a nearby area ~ one (1) inch distant. The formulas were left on the tiles for ten (10) minutes.

They were then rinsed off using running tap water @ twenty five (25) degrees centigrade and full open flow rate. The rinsing procedure used was the same for all Formulas and involved holding the tile at an angle of ~ 45° and passing the section with the formula to be rinsed through the running tap water - taking a count of one thousand (approximately one (1) second) and then returning at the same speed.

Every effort was made to do this as uniformly as possible from tile to tile by paying particular attention to the angle of the tile, the speed with which the tile was passed through the water, the water temperature and the water flow rate.

Photographs were taken of each tile with the Formulas as applied and again about two minutes after rinsing.

Results

None of the formulas had any observable effect upon the solvent based paint or upon the polyurethane foam insulation.

At 36.5%, 25% and 15% some of the roof asphalt was solubilized by both the orange oil and the d-limonene formulas as evidenced by black traces in the area surrounding the area where the tar was applied. Neither 10% nor 5% orange oil or d-limonene showed this effect.

The latex semi gloss paint was softened by all of the formulas, but not removed by any, nor were there any observable differences in softening or wrinkling of the paint between the orange oil and d-limonene formulas.

The lipstick was removed in descending order based upon the concentration of orange oil or d-limonene. No differences were seen between orange oil and d-limonene formulas in removing the lipstick.

The makeup was removed best by the 15% and 10% orange oil or d-limonene containing formulas and not as well by the 36.5%, 25% or 5% orange oil or d-limonene containing formulas.

Conclusions

1. No meaningful differences were seen between the orange oil formulas and the d-limonene formulas in their abilities to remove the test materials.